Remarks

I. Entry of the Amendments filed on March 29, 2005, is Respectfully Requested

Applicants specifically incorporate by reference herein the Amendment and Reply filed on March 29, 2005. Entry of the amendments to the claims presented therein is respectfully requested.

II. Status of the Claims

Upon entry of the amendments to claims 14,16, 18-20 and 44, and newly added claims 58 to 79 presented in the Amendment and Reply filed March 29, 2005 (which is herein incorporated by reference), claims 14-20, 27 and 32-79 are pending in the application, with claims 14, 16 and 44 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

III. Supplemental Advisory Action Withdrew the Previous Advisory Action

In the Supplemental Advisory Action dated June 2, 2005 ("the Supp. Advisory Action"), the Examiner withdrew the Advisory Action mailed on April 20, 2005, ("the withdrawn Advisory Action) and substituted the Supp. Advisory Action to correct for errors in the April 20 Advisory Action. (Supp. Advisory Action at page 2).

IV. Rejection Under 102(f) Has Been Withdrawn

Applicants thank the Examiner for agreeing to withdraw the rejection under 35 U.S.C. § 102(f). (Supp. Advisory Action at page 3.)

V. The Remaining Rejections Under 35 U.S.C. § 102 are Traversed

The Examiner asserts in the Supp. Advisory Action that "[a]lthough applicant changes 'integration sequences' with the term 'mobile genetic element' in the proposed amendment on independent claims 14, 16, and 44, the rejections under 35 USC 102 should be maintained because 'mobile genetic element' is defined as any genetic unit that can insert into a chromosome, exit, and relocate." (Supp. Advisory Action at page 2.) Applicants respectfully traverse these rejections. In maintaining the rejections, the Examiner refers to the definition for "mobile genetic element" apparently obtained from an internet website (http://www.biochmem.northwestern.edu/holmgren/Glossary/Definitions/Def-T/transposable_genetic_eleme.html), that was included with the withdrawn Advisory Action. (Supp. Advisory Action at page 2.) Applicants respectfully disagree with the Examiner's assertions.

In addition to the points already set forth in the Amendment and Reply filed on March 29, 2005 (which is herein incorporated by reference in its entirety), Applicants would like to specifically address the Examiner's comments with respect to the term "mobile genetic element" raised at page 2 of the Supp. Advisory Action.

Applicants respectfully point out that it is clear from the specification of the captioned application what is meant by the term "mobile genetic element." In particular, the specification defines "mobile genetic element" as follows:

> . . .an integration sequence is any nucleotide sequence that is capable of inserting randomly into a target nucleic acid molecule. ***Integration sequences are also known in the art as mobile genetic elements***. Any integration sequence known to those of ordinary skill in the art may be used to practice the present invention, including but not limited to transposons (transposable elements), integrating viruses (e.g.,

> retroviruses), IS elements, retrotransposons, conjugative transposons, P elements of *Drosophila*, bacterial virulence factors, or mobile genetic elements for eukaryotic organisms such as *mariner*, Tc1 and *Sleeping Beauty*. ***Other mobile genetic elements known to those skilled in the art may also be used in accordance with the present invention.***

Specification at page 22, line 29 to page 23, line 9 (emphasis added); *see also*, Specification at page 34, lines 7-29. Therefore, it is unnecessary to look to a dictionary or other extrinsic source to determine the meaning of this claim element. This principle was reinforced by the Federal Circuit in its recent decision in *Phillips v. AWH Corporation*, where they stated that:

> In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.

Phillips, Nos. 03-1269, -1286, slip. op. at 21 (Fed. Cir. Jul. 12, 2005) (en banc).

The court further stated that:

> Properly viewed, the "ordinary meaning" of a claim term is its meaning to the ordinary artisan after reading the entire patent. Yet heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.

Id at 25.

Moreover, the definition cited by the Examiner is actually a definition for the term "transposable genetic element," not the term "mobile genetic element," which is recited in the claims. Although the cited webpage suggests that the term "mobile genetic element" is a synonym for "transposable genetic element," according to the definition provided in the present specification, a "transposable element" is defined as a *type* of mobile genetic element. *See* Specification at page 23, lines 1-4. Applicants respectfully

submit that it is improper for the Examiner to ignore the definition of "mobile genetic element" provided in the specification in favor of a definition gleaned from an internet glossary.

Even adopting the Examiner's definition of "mobile genetic element," the rejections under 35 U.S.C. § 102 should be withdrawn. The Examiner's definition recites that this is "[a] general term for any genetic unit that can insert into a chromosome, exit, ***and*** relocate." *See* (http://www.biochmem.northwestern.edu/holmgren/Glossary/Definitions/Def-T/transposable_genetic_eleme.html), attached to the withdrawn Advisory Action (emphasis added). However, nucleic acid fragments produced, for example, by restriction digest or by random fragmentation are not, simply by virtue of being a nucleic acid fragment, capable of performing all three operations recited in the Examiner's definition of "mobile genetic element"; namely, inserting into a chromosome, exiting, and relocating.

The definition of "mobile genetic element" cited by the Examiner in the Advisory Actions does not establish that any of Stemmer[2], Atlung[3], or Hartley[4], over which the Examiner has maintained the rejections under 35 U.S.C. § 102, disclose all of the elements of the claimed invention, as required for a case of anticipation under 35 U.S.C. § 102. Hence, Applicants respectfully maintain that none of Stemmer, Atlung, or Hartley describes, either expressly or inherently, a method of introducing recombination sites into a nucleic acid molecule by inserting mobile genetic element(s) comprising recombination sites as in the present claims. Accordingly, reconsideration and

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[2] U.S. Patent No. 5,605,793 (Doc. AB3, of record).

[3] Atlung *et al.*, *Gene* 107: 11-17 (1991) (Doc. AT4, of record).

[4] U.S. Patent No. 5,888,732 (Doc. AF3, of record).

withdrawal of the rejections under 35 U.S.C. § 102 (b) over Stemmer and over Atlung, and the rejection under 35 U.S.C. §§ 102 (a) or (e) over Hartley, are respectfully requested.

VI. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and the Supp. Advisory Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Supplemental Reply and the Amendment and Reply filed on March 29, 2005, which is incorporated by reference herein, are respectfully requested.

Respectfully submitted,

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